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10/505,405

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Stewart Cole

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BABIC, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1637

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|------------------------------------|--|
| Office Action Summary | Application No. 10/505,405 | Applicant(s) COLE ET AL. | |
| | Examiner CHRISTOPHER M. BABIC | Art Unit 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 and 23-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-8 is/are rejected.
- 7) ☒ Claim(s) 4,9-14 and 19-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/8/2004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Rules Notice to Comply</u> . |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of, group I, claims 1-14 and 19-22, in the reply filed on April 25, 2008 is acknowledged. The traversal is on the ground(s) that it would not have been obvious for someone skilled in the art, who did not know SEQ ID NO: 1, to isolate and to identify the sequence, which hybridizes to SEQ ID NO:1 under stringent conditions. This is not found persuasive because the question of obviousness is irrelevant to the fact that NEB discloses polynucleotides that meet options C and D of the claimed invention. Furthermore, it appears Applicant has mischaracterized the disclosure of NEB. The NEB product is composed of every permutation of a 24-mer oligonucleotide, not a universal or degenerate primer as recited by Applicant. Thus, the restriction requirement is still deemed proper and hereby made FINAL. As such, claim(s) 15-18 and 23-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the

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attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given time of reply to this office action within which to comply with the sequence rules, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in **abandonment** of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Pages 9 and 36-39, respectively contain sequences without SEQ ID NOs. If these sequences are included in the sequence listing provide by Applicant, the specification should be amended to include the SEQ ID NOs. If these sequences were not included in the sequence listing filed August 4, 2004. Applicant should provide a substitute sequence listing and a CRF that include those sequences.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP

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§ 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Applicant is advised that if an English translation of a cited foreign language reference is not provided, it will not be considered. Abstracts will be considered if a proper translation is provided.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 22. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

a) Claim 6 objected to because of the following informalities: The word "excepted" should be replaced with "except" to provide for appropriate English grammar. Appropriate correction is required.

b) Claims 9, 14, 19, and 21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 9-14 and 19-22 have not been further treated on the merits.

Claim Rejections - 35 USC § 112 - Indefiniteness

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claims are indefinite because the scope of the phrase "characterized in that" is unclear. It is suggested that conventional U.S. claim language such as "comprising" be used in amended claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (U.S. 5,474,796). The rejection of claim 6 is further evidenced by GENBANK Accession Number L26330 (uploaded to NCBI June 4, 1994) and BLAST search completed @ NCBI on August 13, 2008.

With regard to claims 1-3, 7, and 8, Brennan teaches the production of a solid support comprising immobilized extendable oligonucleotides that represent every possible permutation of the 10-mer oligonucleotide (col. 9, example 4, for example). Thus, the product of Brennan inherently contains oligonucleotides that possess 100% identity or homology to 10-mer segments of SEQ ID NO: 1 and 4 as well as oligonucleotides that are perfectly complementary to 10-mer segments of SEQ ID NO: 1 and 4, i.e. options C and D of the claimed invention. Thus, Brennan anticipates the claimed invention.

With regard to claims 5, each primer, SEQ ID NO: 17 or 18, necessarily comprises a 10-mer that was present in the product according to Brennan.

With regard to claim 6, Applicant is reminded that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). Thus, a 8-mer plus nucleotide segment present in both *Mycobacterium tuberculosis* and *Mycobacterium africanum* would meet the claimed limitations. A BLAST search of a known sequence within the *Mycobacterium africanum* genome (Accession Number L26330) revealed a homologous segment within the *Mycobacterium tuberculosis* genome (BLAST result 1, for example). As demonstrated by the BLAST alignment, there are inherently several 10-mer segments, present in both of the above genomes, that were present in the product according to Brennan.

2. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being

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anticipated by New England Biolabs 1998/99 Catalog (NEB Catalog). The rejection of claim 6 is further evidenced by GENBANK Accession Number L26330 (uploaded to NCBI June 4, 1994) and BLAST search completed @ NCBI on August 13, 2008.

With regard to claims 1-3, 7, and 8, page 121 of the NEB Catalog discloses a packaged product for sale (catalog #1255) comprising Random Primer 24. This product comprised every possible primer of 24 bases in length, and therefore inherently anticipates the claimed invention for the reasons presented above (see Brennan).

To determine the certainty that every possible 24 base primer would have been present in this product, the following calculations rely on facts provided on page pg. of the catalog, specifically the mass of 1.0 A₂₆₀ unit of single-stranded DNA and the molecular weight of single-stranded DNA per nucleotide (i.e. half the weight of a double-stranded DNA per basepair).

Random 24-mer:

Molecular weight of 24-mer:

$$24 \times 325 \text{ daltons/nucleotide} = 7,800 \text{ daltons} = 7,800 \text{ g/mol}$$

Number of possible 24-mers:

$$4^{24} = 2.8 \times 10^{14} \text{ molecules}$$

How many molecules of 24-mer in a vial sold by NEB:

$$1 \text{ A}_{260} \text{ unit} = 33 \text{ } \mu\text{g} = 3.3 \times 10^{-5} \text{ g}$$

$$3.3 \times 10^{-5} \text{ g} \div 7,800 \text{ g/mol} = 4.2 \times 10^{-9} \text{ mol}$$

$$(4.2 \times 10^{-9} \text{ mol}) \times (6.02 \times 10^{23} \text{ molecules/mol}) = 2.5 \times 10^{15} \text{ molecules}$$

How many vials needed to sum to 1 of each possible 24-mer:

$$2.8 \times 10^{14} \text{ molecules} \div 2.5 \times 10^{15} \text{ molecules} = 0.11 \text{ vial}$$

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Put another way, one vial of random 24-mer sold by NEB contains enough material to provide nearly 10 molecules of each possible 24-mer; and each vial containing 12, 9, and 6-mer primers would naturally contain even more copies of each possible primer.

Thus, NEB anticipates the claimed invention.

With regard to claims 5, the fragment obtained by amplification with primers, SEQ ID NO: 17 and 18, necessarily comprises a 24-mer that was present in the product according to NEB.

With regard to claim 6, As demonstrated by the BLAST alignment, there are inherently several 24-mer segments, present in both of the above genomes, that were present in the product according to NEB.

Allowable Subject Matter

With regard to claim 4, a search of the prior art revealed no reference teaching or fairly suggesting the oligonucleotide sequences recited in SEQ ID NOs: 17 and 18. Thus, the claim is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Patent Examiner
Art Unit 1637
Technology Center 1600

